

1 MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

2
3 CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
4 COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being
8 sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)
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10 **Section 1. Applicability**

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12 Sec. 1. These standards are requirements for the approval of the initiation, expansion, replacement,
13 or acquisition of CT services and the delivery of services under Part 222 of the Code. Pursuant to Part
14 222 of the Code, CT is a covered clinical service. The Department shall use these standards in applying
15 Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section
16 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
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18 **Section 2. Definitions**

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20 Sec. 2. (1) For purposes of these standards:

21 (a) "Acquisition of an existing CT scanner service" means obtaining possession or control of an
22 existing fixed or mobile CT scanner service or existing CT scanner(s) by contract, ownership, or other
23 comparable arrangement. For proposed projects involving mobile CT scanners, this applies to the central
24 service coordinator and/or host facility.

25 (b) "Billable procedure" means a CT procedure billed as a single unit and performed in Michigan.

26 (c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and
27 including the neck.

28 (d) "Bundled body scan" means two or more body scans billed as one CT procedure.

29 (e) "Central service coordinator" means the organizational unit which has operational responsibility
30 for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

31 (f) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to
32 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

33 (g) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et
34 seq. of the Michigan Compiled Laws.

35 (h) "Computed tomography" or "CT" means the use of radiographic and computer techniques to
36 produce cross-sectional images of the head or body.

37 (i) "CT-angio hybrid unit" means an integrated system comprised of both CT and angiography
38 equipment sited in the same room that is designed specifically for interventional radiology or cardiac
39 procedures. The CT unit is a guidance mechanism and is intended to be used as an adjunct to the
40 procedure. The CT unit shall not be used for diagnostic studies unless the patient is currently undergoing
41 a CT-angio hybrid procedure and is in need of a secondary diagnostic study.

42 (j) "CT equivalents" means the resulting number of units produced when the number of billable
43 procedures for each category is multiplied by its respective conversion factor tabled in Section 16.

44 (k) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head,
45 other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT
46 scanner hybrids if used for CT only procedures. The term does not include emission-computed
47 tomographic systems utilizing internally administered single-photon gamma ray emitters, positron
48 annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators
49 used solely for treatment planning purposes in conjunction with an MRT unit, non-diagnostic, intra-
50 operative guidance tomographic units, and dental CT scanners that generate a peak power of 5 kilowatts
51 or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate
52 dental procedures by a licensed dentist under the practice of dentistry.

53 (l) "CT scanner services" means the CON-approved utilization of a CT scanner(s) at one site in the
54 case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

55 (m) "CT-GUIDED ABLATION" MEANS ANY INVASIVE PROCEDURE PERFORMED IN A CT
56 SCANNER REQUIRING CT GUIDANCE OF A NEEDLE OR OTHER DEVICE TO TREAT A TUMOR.

57 (n) "CT-GUIDED NON-ABLATION PROCEDURE" MEANS ANY INVASIVE PROCEDURE,
58 REQUIRING CT GUIDANCE, PERFORMED IN THE CT SCANNER OTHER THAN CT-GUIDED
59 ABLATIONS.

60 (o) "Dedicated pediatric CT" means a fixed CT scanner on which at least 70% of the CT procedures
61 are performed on patients under 18 years of age.

62 (p) "Department" means the Michigan Department of Health and Human Services (MDHHS).

63 (q) "Emergency room" means a designated area physically part of a licensed hospital and
64 recognized by the Department as having met the staffing and equipment requirements for the treatment
65 of emergency patients.

66 (r) "Excess CT Equivalents" means the number of CT equivalents performed by an existing CT
67 scanner service in excess of 10,000 per fixed CT scanner and 4,500 per mobile CT scanner or either an
68 existing fixed or mobile CT scanner service, the number of CT scanners used to compute excess CT
69 equivalents shall include both existing and approved but not yet operational CT scanners. In the case of
70 a CT scanner service that operates or has a valid CON to operate that has more than one fixed CT
71 scanner at the same site, the term means number of CT equivalents in excess of 10,000 multiplied by the
72 number of fixed CT scanners at the same site. For example, if a CT scanner service operates, or has a
73 valid CON to operate, two fixed CT scanners at the same site, the excess CT equivalents is the number
74 that is in excess of 20,000 (10,000 x 2) CT equivalents. In the case of an existing mobile CT scanner
75 service, the term means the sum of all CT equivalents performed by the same mobile CT scanner service
76 at all of the host sites combined that is in excess of 4,500. For example, if a mobile CT scanner service
77 serves five host sites with 1 mobile CT scanner, the term means the sum of CT equivalents for all five
78 host sites combined that is in excess of 4,500 CT equivalents.

79 (s) "Existing CT scanner service" means the utilization of a CON-approved and operational CT
80 scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a
81 mobile CT scanner service.

82 (t) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT
83 scanner services.

84 (u) "Existing mobile CT scanner service" means a CON-approved and operational CT scanner and
85 transporting equipment operated by a central service coordinator serving two or more host sites.

86 (v) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an
87 existing CT scanner service.

88 (w) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or
89 posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

90 (x) "Health Service Area" or "HSA" means the groups of counties listed in Appendix A.

91 (y) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

92 (z) "Hospital-based portable CT scanner or portable CT scanner" means a CT scanner capable of
93 being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide high-quality
94 imaging of critically ill patients.

95 (aa) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner
96 services.

97 (abb) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or
98 mobile, at a site that does not perform CT scans as of the date an application is submitted to the
99 Department. The term does not include the acquisition or replacement of an existing CT scanner service
100 at the existing site or to a different site or the renewal of a lease.

101 (acc) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

102 (bdd) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a
103 central service coordinator and which must serve two or more host facilities.

104 (eee) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is
105 authorized to serve.

106 (edff) "Pediatric patient" means any patient less than 18 years of age.

107 (eegg) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that
108 requires a change in the radiation safety certificate, proposed by an applicant which results in that
109 applicant operating the same number of CT scanners before and after project completion, at the same
110 geographic location. The term also includes relocating an existing CT scanner or CT scanner service
111 from an existing site to a different site.

112 (fhh) "Sedated patient" means a patient that meets all of the following:

113 (i) Patient undergoes procedural sedation and whose level of consciousness is either moderate
114 sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the
115 American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care
116 Organizations, or an equivalent definition.

117 (ii) Who requires observation by personnel, other than technical employees routinely assigned to the
118 CT unit, who are trained in cardiopulmonary resuscitation (CPR) and pediatric advanced life support
119 (PALS).

120 (ii) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the
121 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
122 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
123 disorders, and other conditions that make the patient unable to comply with the positional requirements of
124 the exam.

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126 (2) Terms defined in the Code have the same meanings when used in these standards.

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128 **Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service**

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130 Sec. 3. An applicant proposing to initiate a CT scanner service, other than a hospital-based portable
131 CT scanner service, shall demonstrate the following, as applicable:

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133 (1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the
134 following:

135 (a) The proposed site is a hospital licensed under Part 215 of the Code.

136 (b) The hospital operates an emergency room that provides 24-hour emergency care services as
137 authorized by the local medical control authority to receive ambulance runs.

138

139 (2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),
140 proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT
141 equivalents per year for the second 12-month period after beginning operation of the CT scanner.

142

143 (3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of
144 at least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the
145 CT scanner.

146

147 (4) An applicant proposing to initiate CT scanner services as an existing host site on a different
148 mobile CT scanner service shall demonstrate the following:

149 (a) The applicant provides a proposed route schedule.

150 (b) The applicant provides a draft contract for services between the proposed host site and central
151 service coordinator.

152

153 **Section 4. Requirements for approval for applicants proposing to expand an existing CT scanner service**

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155

156 Sec. 4. An applicant proposing to expand an existing CT scanner service, other than a hospital-based
157 portable CT scanner service, shall demonstrate the following, as applicable:
158

159 (1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate that all
160 of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 8, 9, and 12,
161 have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most recent
162 continuous 12-month period preceding the applicant's request. In computing this average, the
163 Department will divide the total number of CT equivalents performed by the applicant's total number of
164 fixed CT scanners, including both operational and approved but not operational fixed CT scanners.
165

166 (2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to
167 Section 12 shall demonstrate that all of the applicant's dedicated pediatric CT scanners have performed
168 an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent
169 continuous 12-month period preceding the applicant's request. In computing this average, the
170 Department will divide the total number of CT equivalents performed by the applicant's total number of
171 dedicated pediatric CT scanners, including both operational and approved but not operational dedicated
172 pediatric CT scanners.
173

174 (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall
175 demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500
176 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the
177 applicant's request. In computing this average, the Department will divide the total number of CT
178 equivalents performed by the applicant's total number of mobile CT scanners, including both operational
179 and approved but not operational mobile CT scanners.
180

181 **Section 5. Requirements for approval for applicants proposing to replace an existing CT scanner** 182

183 Sec. 5. An applicant proposing to replace an existing CT scanner or service, other than a hospital-
184 based portable CT scanner service, shall demonstrate the following, as applicable:
185

186 (1) An applicant proposing to replace an existing fixed, mobile, or dedicated pediatric CT scanner
187 shall demonstrate all of the following:

- 188 (a) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.
- 189 (b) The existing CT scanner(s) proposed to be replaced is fully depreciated according to generally
190 accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the
191 public, or, that the proposed replacement CT scanner offers technological improvements which enhance
192 quality of care, increase efficiency, and/or reduce operating costs and patient charges.
193

194 (2) An applicant proposing to replace an existing fixed CT scanner service to a different site shall
195 demonstrate that the proposed project meets all of the following:

196 (a) The existing fixed CT scanner service to be replaced has been in operation for at least 36 months
197 as of the date an application is submitted to the Department unless the applicant meets the requirement
198 in subsection (c)(ii) or (iii).

199 (b) The proposed new site is within a 10-mile radius of a site at which an existing fixed CT scanner
200 service is located if an existing fixed CT scanner service is located in a metropolitan statistical area
201 county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan
202 statistical area county.

203 (c) The CT scanner service to be replaced performed at least an average of 7,500 CT equivalents
204 per fixed scanner in the most recent 12-month period for which the Department has verifiable data unless
205 one of the following requirements are met:

- 206 (i) An applicant meets all of the requirements of Section 3(1);

- 207 (ii) the owner of the building where the site is located has incurred a filing for bankruptcy under
208 Chapter Seven (7) within the last three years;
- 209 (iii) the ownership of the building where the site is located has changed within 24 months of the date
210 of the service being operational; or
- 211 (iv) the CT service being replaced is part of the replacement of an entire hospital to a new geographic
212 site and has only one (1) CT unit.
- 213 (d) The applicant agrees to operate the CT scanner service in accordance with all applicable project
214 delivery requirements set forth in Section 14 of these standards.

- 215
- 216 (3) An applicant proposing to replace a fixed CT scanner(s) of an existing CT scanner service to a
217 different site shall demonstrate that the proposed project meets all of the following:
- 218 (a) The existing CT scanner service from which the CT scanner(s) is to be replaced has been in
219 operation for at least 36 months as of the date an application is submitted to the Department.
- 220 (b) The proposed new site is within a 10-mile radius of a site at which an existing fixed CT scanner
221 service is located if an existing fixed CT scanner service is located in a metropolitan statistical area
222 county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan
223 statistical area county.
- 224 (c) Each existing CT scanner at the service from which a scanner is to be replaced performed at
225 least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which
226 the Department has verifiable data.
- 227 (d) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all
228 applicable project delivery requirements set forth in Section 14 of these standards.
- 229 (e) For volume purposes, the new site shall remain associated with the existing CT service for a
230 minimum of three years.

231

232 **Section 6. Requirements for approval for applicants proposing to acquire an existing CT scanner**
233 **service or an existing CT scanner(s)**

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235 Sec. 6. An applicant proposing to acquire an existing fixed or mobile CT scanner service, other than a
236 hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

- 237
- 238 (1) The applicant shall not be required to be in compliance with the volume requirement applicable to
239 the seller/lessor on the date the acquisition occurs if the proposed project meets one of the following:
- 240 (a) It is the first acquisition of the existing fixed or mobile CT scanner service for which a final
241 decision has not been issued after June 4, 2004.
- 242 (b) The existing fixed or mobile CT scanner service is owned by, is under common control of, or has
243 a common parent as the applicant, and the CT scanner service shall remain at the same site.
- 244
- 245 (2) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an
246 applicant shall be required to demonstrate the following, as applicable:
- 247 (a) The fixed CT scanner service to be acquired performed at least 7,500 CT equivalents per fixed
248 CT scanner in the most recent 12-month period for which the Department has verifiable data, unless an
249 applicant meets all of the requirements of Section 3(1) or meets the requirements of Section 6(1)(b).
- 250 (b) The mobile CT scanner service to be acquired performed at least 3,500 CT equivalents per
251 mobile CT scanner in the most recent 12-month period for which the Department has verifiable data,
252 unless an applicant meets the requirements of Section 6(1)(b).
- 253
- 254 (3) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or
255 mobile CT scanner service shall demonstrate that the proposed project meets the following:
- 256 (a) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an
257 existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate the following,
258 as applicable:

- 259 (i) The fixed CT scanner(s) to be acquired performed at least 7,500 CT equivalents per fixed CT
260 scanner in the most recent 12-month period for which the department has verifiable data.
261 (ii) The mobile CT scanner(s) to be acquired performed at least 3,500 CT equivalents per mobile CT
262 scanner in the most recent 12-month period for which the Department has verifiable data.
263

264 (4) The CT scanner service shall be operating at the applicable volume requirements set forth in
265 Section 14 of these standards in the second 12 months after the date the service is acquired, and
266 annually thereafter.
267

268 **Section 7. Requirements for a dedicated research fixed CT scanner**

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270 Sec. 7. An applicant proposing to add a fixed CT scanner to an existing CT scanner service for
271 exclusive research use shall demonstrate the following:
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273 (1) The applicant agrees that the dedicated research CT scanner will be used primarily (70% or more
274 of the scans) for research purposes.
275

276 (2) The dedicated research CT scanner shall operate under a protocol approved by the applicant's
277 Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.
278

279 (3) The proposed site can have no more than three dedicated research fixed CT scanners approved
280 under this section.
281

282 (4) The dedicated research scanner approved under this section may not utilize CT procedures
283 performed on the dedicated CT scanner to demonstrate need or to satisfy CT CON review standards
284 requirements.
285

286 **Section 8. Requirements for approval of a hospital-based portable CT scanner for initiation, 287 expansion, replacement, and acquisition**

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289 Sec. 8. An applicant proposing to initiate, expand, replace, or acquire a hospital-based portable CT
290 scanner shall demonstrate that it meets all of the following:
291

292 (1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two
293 hospital-based portable CT scanners.
294

295 (2) The proposed site is a hospital licensed under Part 215 of the Code.
296

297 (3) The hospital has been certified as a level I or level II trauma facility by the American College of
298 Surgeons, or has performed >100 craniotomies in the most recent 12- month period verifiable by the
299 Department.
300

301 (4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all
302 applicable project delivery requirements set forth in Section 14 of these standards.
303

304 (5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.
305

306 (6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner
307 to demonstrate need or to satisfy CT CON review standards requirements.
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309 **Section 9. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement, 310 and acquisition**

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Sec. 9. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project delivery requirements set forth in Section 14 of these standards.

(3) The approved PET/CT hybrid will not be subject to CT volume requirements.

(4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid scanner to demonstrate need or to satisfy CT CON review standards requirements.

Section 10. Requirements for approval of a CT-angio hybrid unit for initiation, replacement, and acquisition

Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital-based CT-angio hybrid unit shall demonstrate each of the following, as applicable to the proposed project:

(1) The proposed site is a licensed hospital under Part 215 of the Code.

(2) The proposed site has an existing fixed CT scanner service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site offers the following services:

- (a) diagnostic cardiac catheterization; or
- (b) interventional radiology; or
- (c) surgical services

(4) The proposed CT-angio hybrid unit must be located in one of the following rooms:

- (a) cardiac catheterization lab; or
- (b) interventional radiology suite; or
- (c) licensed operating room

(5) Diagnostic CT studies shall not be performed on a CT-angio hybrid unit approved under this section unless the patient is currently undergoing a CT-angio hybrid interventional procedure and is in need of a secondary diagnostic CT study.

(6) The approved CT-angio hybrid shall not be subject to CT volume requirements.

(7) The applicant shall not utilize the procedures performed on the CT-angio hybrid unit to demonstrate need or to satisfy CT CON review standards requirements.

Section 11. Additional requirements for approval of a mobile CT scanner service

Sec. 11. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall demonstrate that it meets all of the following additional requirements:

(a) A separate CON application shall be submitted by the central service coordinator and each Michigan host facility.

363 (b) The normal route schedule, the procedures for handling emergency situations, and copies of all
364 potential contracts related to the mobile CT scanner service shall be included in the CON application
365 submitted by the central service coordinator.
366

367 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall
368 demonstrate that it meets all of the following additional requirements:

369 (a) Approval of the application will not result in an increase in the number of operating mobile CT
370 scanners for the mobile CT scanner network unless the requirements of Section 4 have been met.

371 (b) A separate CON application has been filed for each host facility.
372

373 **Section 12. Requirements for approval of an applicant proposing to establish dedicated pediatric** 374 **CT Scanner**

375
376 Sec. 12. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the
377 following:

378 (a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges
379 (excluding normal newborns) in the most recent year of operation.

380 (b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most
381 recent year of operation.

382 (c) The applicant shall have an active medical staff, at the time the application is submitted to the
383 Department that includes, but is not limited to, physicians who are fellowship-trained in the following
384 pediatric specialties:

385 (i) pediatric radiology (at least two)

386 (ii) pediatric anesthesiology

387 (iii) pediatric cardiology

388 (iv) pediatric critical care

389 (v) pediatric gastroenterology

390 (vi) pediatric hematology/oncology

391 (vii) pediatric neurology

392 (viii) pediatric neurosurgery

393 (ix) pediatric orthopedic surgery

394 (x) pediatric pathology

395 (xi) pediatric pulmonology

396 (xii) pediatric surgery

397 (xiii) neonatology

398 (d) The applicant shall have in operation the following pediatric specialty programs at the time the
399 application is submitted to the Department:

400 (i) pediatric bone marrow transplant program

401 (ii) established pediatric sedation program

402 (iii) pediatric open heart program
403

404 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the
405 requirements of Section 3 of these standards.
406

407 **Section 13. Requirements for Medicaid participation**

408
409 Sec. 13. An applicant shall provide verification of Medicaid participation. An applicant that is a new
410 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
411 to the Department within six (6) months from the offering of services if a CON is approved.
412

413 **Section 14. Project delivery requirements and terms of approval for all applicants**

414

415 Sec. 14. An applicant shall agree that, if approved, the CT scanner(s) services shall be delivered in
416 compliance with the following terms of approval.

417
418 (1) Compliance with these standards.

419
420 (2) Compliance with the following quality assurance standards:

421 (a) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

422 (i) The screening of requests for CT procedures and interpretation of CT procedures will be
423 performed by physicians with training and experience in the appropriate diagnostic use and interpretation
424 of cross-sectional images of the anatomical region(s) to be examined, and

425 (ii) The CT scanner is operated by physicians and/or is operated by radiological technologists
426 qualified by training and experience to operate the CT scanner safely and effectively.

427 For purposes of evaluating (a)(i), the Department shall consider it prima facie evidence of a
428 satisfactory assurance mechanism as to screening and interpretation if the applicant requires the
429 screening of requests for and interpretations of CT procedures to be performed by physicians who are
430 board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional
431 imaging of a specific organ system. For purposes of evaluating (a)(i) the Department shall consider it
432 prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the
433 applicant requires the CT scanner to be operated by a physician or by a technologist registered by the
434 American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical
435 Radiography Technologists (ARCRT). However, the applicant may submit and the Department may
436 accept other evidence that the applicant has established a mechanism to assure that the CT scanner
437 facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT
438 scanner.

439 (b) The applicant shall employ or contract with a radiation physicist to review the quality and safety of
440 the operation of the CT scanner.

441 (c) The applicant shall assure that at least one of the physicians responsible for the screening and
442 interpretation as defined in subsection (a)(i) will be in the CT facility or available (either on-site or through
443 telecommunication capabilities) to make the final interpretation.

444 (d) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so
445 authorized by the applicant to interpret initial scans will be on-site or available through telecommunication
446 capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation
447 of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (a)(i)
448 within 24 hours.

449 (e) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical
450 emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other
451 appropriate emergency interventions, and a physician on site in or immediately available to the CT
452 scanner at all times when patients are undergoing scans.

453 (f) Fixed CT scanner services shall be made available 24 hours a day for emergency patients if the
454 facility operates an emergency room that provides 24-hour emergency care services as authorized by the
455 local medical control authority to receive ambulance runs.

456 (g) The applicant shall accept referrals for CT scanner services from all appropriately licensed
457 practitioners.

458 (h) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its
459 equivalent) requirement that provides for the medical and administrative control of the ordering and
460 utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance.
461 These responsibilities may be assigned to an existing body of the applicant, as appropriate.

462 (i) An applicant approved under Section 12 must be able to prove that all radiologists, technologists
463 and nursing staff working with CT patients have continuing education or in-service training on pediatric
464 low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

465
466 (3) Compliance with the following access to care requirements:

- 467 (a) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan
468 population, shall:
- 469 (i) not deny any CT scanner services to any individual based on ability to pay or source of payment;
 - 470 (ii) provide all CT scanning services to any individual based on the clinical indications of need for the
471 service; and
 - 472 (iii) maintain information by payor and non-paying sources to indicate the volume of care from each
473 source provided annually.
- 474 (b) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
475 of operation and continue to participate annually thereafter.
- 476 (c) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA
477 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

478
479 Compliance with selective contracting requirements shall not be construed as a violation of this term.
480

481 (4) Compliance with the following monitoring and reporting requirements:

482 (a) The approved CT scanners shall be operating AS FOLLOWS FOR THE SECOND 12-MONTH
483 PERIOD AFTER BEGINNING OPERATION OF THE CT SCANNER, AND ANNUALLY THEREAFTER,
484 EXCEPT FOR THOSE SCANNERS EXEMPT UNDER APPLICABLE SECTIONS:

485 (i) at an average of 7,500 CT equivalents ~~scanner~~ per fixed scanner PER YEAR UNLESS ONE
486 OF THE FOLLOWING HAS BEEN MET:

487 (A) 5,000 CT EQUIVALENTS PER FIXED SCANNER PER YEAR FOR CT SERVICES WITH ONE
488 FIXED SCANNER.

489 (B) 2,500 CT EQUIVALENTS PER FIXED SCANNER PER YEAR FOR CT SERVICES WITH ONE
490 FIXED SCANNER LOCATED OUTSIDE THE 20-MILE RADIUS FROM THE NEXT CLOSEST FIXED CT
491 SERVICE.

492 (C) A HOSPITAL, WITH ONE FIXED SCANNER, LICENSED UNDER PART 215 OF THE CODE
493 THAT OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE
494 SERVICES AS AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE
495 AMBULANCE RUNS SHALL NOT HAVE A MINIMUM ANNUAL VOLUME REQUIREMENT FOR
496 PURPOSES OF THIS SECTION.

497 (D) A FREESTANDING SURGICAL OUTPATIENT FACILITY (FSOF), WITH ONE FIXED
498 SCANNER, LICENSED UNDER PART 208 OF THE CODE THAT OPERATES AN EMERGENCY ROOM
499 THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AS AUTHORIZED BY THE LOCAL
500 MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS SHALL NOT HAVE A MINIMUM
501 ANNUAL VOLUME REQUIREMENT FOR PURPOSES OF THIS SECTION.

502 (E) AN OFF-CAMPUS EMERGENCY DEPARTMENT OF A HOSPITAL, LICENSED UNDER PART
503 215 OF THE CODE, WITH ONE FIXED SCANNER, THAT HAS OBTAINED PROVIDER-BASED
504 STATUS UNDER 42 CFR 413.65, THAT IS AVAILABLE FOR TREATING EMERGENCY PATIENTS 24
505 HOURS A DAY, 7 DAYS A WEEK, AND AUTHORIZED BY THE LOCAL MEDICAL CONTROL
506 AUTHORITY TO RECEIVE AMBULANCE RUNS SHALL NOT HAVE A MINIMUM ANNUAL VOLUME
507 REQUIREMENT FOR PURPOSES OF THIS SECTION.

508 (ii) and ~~31~~ 500 CT equivalents per mobile scanner per year for the second 12-month period after
509 beginning operation of the CT scanner, and annually thereafter, except for those scanners exempt under
510 applicable sections.

511
512 (b) The applicant shall participate in a data collection network established and administered by the
513 Department or its designee. The data may include, but is not limited to, annual budget and cost
514 information, operating schedules, through-put schedules, demographic and diagnostic information, the
515 volume of care provided to patients from all payor sources, and other data requested by the Department,
516 and approved by the Commission. The applicant shall provide the required data on a separate basis for
517 each separate and distinct site as required by the Department; in a format established by the Department;

518 and in a mutually agreed upon media. The Department may elect to verify the data through on-site
519 review of appropriate records.

520 (c) Equipment to be replaced shall be removed from service.

521 (d) The applicant shall provide the Department with timely notice of the proposed project
522 implementation consistent with applicable statute and promulgated rules.

523

524 (5) An applicant approved under Section 8 shall be in compliance with the following:

525 (a) Portable CT scanner can only be used by a qualifying program for the following purposes:

526 (i) Brain scanning of patients being treated in an adult or pediatric Intensive Care Unit (ICU).

527 (ii) Non-diagnostic, intraoperative guidance in an operating room.

528 (b) The approved applicant must provide annual reports to the Department by January 31st of each
529 year for the preceding calendar year. This requirement applies to all applicants approved under Section

530 8.

531 (c) The following data must be reported to the Department:

532 (i) Number of adult studies (age \geq 18)

533 (ii) Number of pediatric studies (age $<$ 18)

534 (iii) Number of studies performed using a portable CT on the same patient while that patient is in an
535 ICU

536

537 (6) An applicant approved under Section 10 shall be in compliance with the following:

538 (a) The proposed site offers the following services:

539 (i) diagnostic cardiac catheterization; or

540 (ii) interventional radiology; or

541 (iii) surgical services

542 (b) The proposed CT-Angio hybrid unit must be located in one of the following rooms:

543 (i) cardiac catheterization lab; or

544 (ii) interventional radiology suite; or

545 (iii) licensed operating room

546

547 (7) The agreements and assurances required by this section shall be in the form of a certification
548 agreed to by the applicant or its authorized agent.

549

550 **Section 15. Project delivery requirements and additional terms of approval for applicants** 551 **involving mobile CT scanners**

552

553 Sec. 15. (1) In addition to the provisions of Section 14, an applicant for a mobile CT scanner shall
554 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the
555 following terms of CON approval:

556 (a) A host facility shall submit only one CON application for a CT scanner for review at any given
557 time.

558 (b) A mobile CT scanner with an approved CON shall notify the Department prior to ending service
559 with an existing host facility.

560 (c) A CON shall be required to add a host facility.

561 (d) A CON shall be required to change the central service coordinator.

562 (e) Each host facility must have at least one board certified or board eligible radiologist on its medical
563 staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion protocol,
564 and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

565 (f) Each mobile CT scanner service must have an Operations Committee with members
566 representing each host facility, the central service coordinator, and the central service medical director.
567 This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route
568 schedule, identify the process by which changes are to be made to the schedule, develop procedures for

569 handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a
570 quarterly basis.

571 (g) The central service coordinator shall arrange for emergency repair services to be available 24
572 hours each day for the mobile CT scanner as well as the vehicle transporting the equipment. In addition,
573 to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on
574 the CT scanner at least once each work day and routine maintenance services shall be provided on a
575 regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

576 (h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner of
577 sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for
578 patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host
579 facility must also provide the capability for processing the film and maintaining the confidentiality of
580 patient records. A communication system must be provided between the mobile vehicle and each host
581 facility to provide for immediate notification of emergency medical situations.

582 (i) A mobile CT scanner service shall operate under a contractual agreement that includes the
583 provision of CT scanner services at each host facility on a regularly scheduled basis.

584 (j) The volume of utilization at each host facility shall be reported to the Department by the central
585 service coordinator under the terms of Section 14(2)(i).

586
587 (2) The agreements and assurances required by this section shall be in the form of a certification
588 agreed to by the applicant or its authorized agent.

590 Section 16. Determination of CT Equivalents

591
592 Sec. 16. CT equivalents shall be calculated as follows:

593
594 (a1) Each billable procedure for the time period specified in the applicable section(s) of these
595 standards shall be assigned to a category set forth in Table 1.

596
597 (b2) The number of billable procedures for each category in the time period specified in the applicable
598 section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to
599 determine the number of CT equivalents for that category for that time period.

600
601 (c3) The number of CT equivalents for each category shall be summed to determine the total CT
602 equivalents for the time period specified in the applicable section(s) of these standards.

603
604 (d4) THE WEIGHTING IN TABLE 1 IS BASED ON TYPICAL TREATMENT TIMES AND ASSUMES
605 THE CONVERSION FACTOR EQUALS APPROXIMATELY 15 MINUTES OF TIME ON THE CT UNIT.

606
607 (5) The conversion factor for pediatric/special needs patients does not apply to procedures
608 performed on a dedicated pediatric CT scanner.

609

610 Table 1	611 Number of		612 Conversion		613 CT
614 Category	615 Billable CT		616 Factor		617 Equivalents
	618 Procedures				
619 <u>Adult Patient</u>					
620 Head Scans w/o Contrast	_____	X	1.00	=	_____
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____

621	Bundled body Scan	_____	X	3.50	=	_____
622	CT-GUIDED NON-ABLATION					
623	PROCEDURE	_____	X	4.00	=	_____
624	CT-GUIDED ABLATION	_____	X	8.00	=	_____
625						
626	<u>Pediatric/Special Needs Patient</u>					
627	Head scans w/o Contrast	_____	x	1.25	=	_____
628	Head Scans with Contrast	_____	x	1.50	=	_____
629	Head Scans w/o & with Contrast	_____	x	2.00	=	_____
630	Body Scans w/o Contrast	_____	x	1.75	=	_____
631	Body Scans with Contrast	_____	x	2.00	=	_____
632	Body Scans w/o & with Contrast	_____	x	3.00	=	_____
633	Bundled body Scan	_____	X	4.00	=	_____
634	CT-GUIDED NON-ABLATION					
635	PROCEDURE	_____	X	4.25	=	_____
636	CT-GUIDED ABLATION	_____	X	8.25	=	_____
637						
638	Total CT Equivalents	_____				_____

640 **Section 17. Documentation of projections**

642 Sec. 17. An applicant required to project volumes under Section 3 shall demonstrate the following, as applicable:

644 (1) An applicant required to project under Section 3 shall demonstrate that the projection is based on historical physician referrals that resulted in an actual scan for the most recent 12-month period immediately preceding the date of the application. Historical physician referrals will be verified with the data maintained by the Department through its "Annual Hospital statistical survey" and/or "Annual Freestanding Statistical Survey."

650 (2) An applicant shall demonstrate that the projected number of referrals to be performed at the proposed site under subsection (1) are from an existing CT scanner service that is in compliance with the volume requirements applicable to that service, and will continue to be in compliance with the volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner service by an applicant. Only excess CT equivalents equal to or greater than what is being committed pursuant to this subsection may be used to document projections under subsection (1). In demonstrating compliance with this subsection, an applicant shall provide each of the following:

657 (a) A written commitment from each referring physician that he or she will refer at least the volume of CT scans to be transferred to the proposed CT scanner service for no less than 3 years subsequent to the initiation of the CT scanner service proposed by an applicant.

660 (b) The number of referrals committed must have resulted in an actual CT scan of the patient at the existing CT scanner service from which referral will be transferred. The committing physician must make available HIPAA compliant audit material if needed upon Department request to verify referral sources and outcomes. Commitments must be verified by the most recent data set maintained by the Department through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey."

665 (c) The projected referrals are from an existing CT scanner service within a 75-mile radius for rural and micropolitan statistical area counties or 20-mile radius for metropolitan statistical area counties.

668 **Section 18. Effect on prior CON review standards; comparative reviews**

670 Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on September 2521, 2014-2016 and effective on December 229, 2014-2016.

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(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

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Counties assigned to each of the health service areas are as follows:

HEALTH SERVICE AREA	COUNTIES		
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton Eaton	Hillsdale Ingham	Jackson Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon Schoolcraft

APPENDIX B

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Rural Michigan counties are as follows:

Alcona	Gogebic	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Montmorency	Schoolcraft
Emmet	Newaygo	Tuscola
Gladwin	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Hillsdale	Mason
Alpena	Houghton	Mecosta
Benzie	Ionia	Menominee
Branch	Isabella	Missaukee
Chippewa	Kalkaska	St. Joseph
Delta	Keweenaw	Shiawassee
Dickinson	Leelanau	Wexford
Grand Traverse	Lenawee	
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Jackson	Muskegon
Bay	Kalamazoo	Oakland
Berrien	Kent	Ottawa
Calhoun	Lapeer	Saginaw
Cass	Livingston	St. Clair
Clinton	Macomb	Van Buren
Eaton	Midland	Washtenaw
Genesee	Monroe	Wayne
Ingham	Montcalm	

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget